

JAN 14 2005

K 042168

7.0 PREMARKET NOTIFICATION 510(k) SUMMARY**510(k) Number:** TO BE ASSIGNED**Date Prepared:** August 10, 2004**Applicant Information:**

Applicant: Advanced Biomaterial Systems, Inc.
100 Passaic Avenue
Chatham, NJ 07928

Contact: John P. Carr
Chief Operating Officer

Telephone: (973) 635-9040
Facsimile: (973) 635-9878

Registration: To be assigned**Device Information:**

Trade Name: Symphony™ VR Radiopaque Bone Cement

Common Name: PMMA Bone Cement (For Vertebroplasty)

Product Code: NDN

Classification Name: Filler, Bone Cement (For Vertebroplasty)

Regulation Class: Class II

Regulation Number: 21 CFR §888.3027

Device Description: Symphony™ VR Radiopaque Bone Cement is a PMMA bone cement made of the same chemical components as Advanced Biomaterial Systems, Inc. CONCERT® Radiopaque Bone Cement.

Symphony™ VR Radiopaque Bone Cement is provided as a two-component product. The polymer powder consists of a PMMA copolymer (polymethyl methacrylate and methyl methacrylate-styrene copolymer) with barium sulfate as the radiopacifier and benzoyl peroxide as the initiator. The liquid component consists of methyl methacrylate monomer, which includes hydroquinone as the stabilizer and N:N dimethyl-p-toluidine as the activator.

Predicate Devices: K033801: Kyphon Inc. – KyphX® HV-R Bone Cement

K032945: Stryker Spineplex™ Radiopaque Bone Cement

N017004: Howmedica Osteonics Surgical Simplex® P
Radiopaque Bone Cement

Intended Use:

Symphony™ VR Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

The following table compares the chemical composition of Symphony™ VR Radiopaque Bone Cement compared to the predicate devices.

Chemical Composition	Symphony™ VR	KyphX® HV-R	Stryker Spineplex™
<i>Powder</i>	20 g (half-dose) Bottle of Sterile Powder	20 g (half-dose) Packet of Sterile Powder	20 g (half-dose) Packet of Sterile Powder
Polymethyl Methacrylate / Methyl Methacrylate-styrene copolymer	71.3% w/w	68.0% w/w	69.1% w/w
Barium sulfate	28.0% w/w	30.0% w/w	30.0% w/w
Benzoyl peroxide	0.7% w/w	2.0% w/w	0.9% w/w
<i>Liquid</i>	8.2g (half-dose) Vial of Sterile Liquid	9.0g (half-dose) Vial of Sterile Liquid	9.4 (half-dose) Vial of Sterile Liquid
Methyl Methacrylate	99.0% v/v	99.1% v/v	97.4% v/v
N: N Dimethyl-p-toluidine	1.0% v/v	0.9% v/v	2.6% v/v
Hydroquinone	100 ppm	75 ppm	75 ± 15 ppm

Summary:

Based on the device performance information provided in this premarket notification, Symphony™ VR Radiopaque Bone Cement has been shown to be substantially equivalent to the currently marketed predicate devices. This device has the same intended use, functional characteristics, material properties, biocompatibility and clinical application as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 14 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John P. Carr
Chief Operating Officer
Advanced Biomaterial Systems
100 Passaic Avenue
Chatham, New Jersey 07928

Re: K042168

Trade/Device Name: Symphony™VR Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate Bone Cement
Regulatory Class: II
Product Code: NDN
Dated: December 17, 2004
Received: December 20, 2004

Dear Mr. Carr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

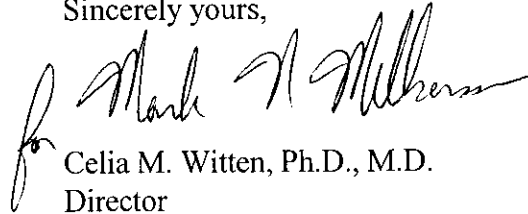
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. John P. Carr

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510 (k) Number (if known): K042168

Device Name: Symphony™ VR Radiopaque Bone Cement

Indications For Use:

Symphony™ VR Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

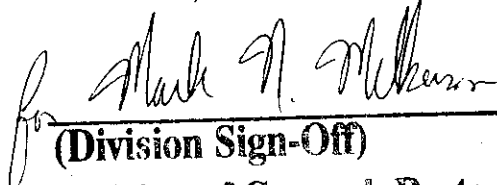
Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K042168